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Quality Evaluation of Clinical Biochemistry Laboratory against ISO 15189:2007 Standard

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ABSTRACT:
Background: The NABL standard provides an opportunity to continually improve the quality clinical lab test results. **Objective:** The study was conducted to evaluate the compliance of biochemistry lab test as per ISO 15189:2007 standard. **Methodology:** A prospective study was conducted in a tertiary-care cardiac center of southern India. A validated check list consists of pre-analytical, analytical, post-analytical phases of lab test based on ISO standard was used to evaluate 30 samples for 21 blood parameters. **Result:** In Pre analytical phase, 21 parameters were evaluated using the checklists, which showed an average of approximately 82% of compliance whereas the analytical phase evident an approximate 97% and the Post analytical showed 74% respectively. **Conclusion:** The result of the study gives an insight to look into the areas of clinical biochemistry lab where the improvement is required in achieving quality test results in compliance with ISO standards.

Key Words: National Accreditation Board for Testing and Calibration Laboratories, ISO/IEC, Standard, Laboratory, Biochemistry, Quality Evaluation, Quality Assurance

INTRODUCTION

Laboratory results are important in making most of the medical decisions. Lab investigations are sensitive and specific compare to clinical decision alone, more over it provides justification for the clinical decision taken. In recent years accreditation emerged as a framework for providing quality medical laboratory services. In current scenario, the laboratories getting accredited may be very few in number but accreditation had improved the quality of laboratory testing by reduction of testing errors. The accredited laboratories are featured to be more accountable and less dependent on external services. The variability in test results and the error frequency can be reduced by implementing and monitoring laboratory quality management system. The accreditation of the laboratory evident that the functioning of it is according to the established quality and competency standards and also complying with set criteria [1].

In India accreditation for medical laboratories is not mandatory. All laboratories only have to register themselves with the health departments in the respective states. The only accreditation agency that is authorized by the central government is the National Accreditation Board for Testing and Calibration of Laboratories (NABL). An estimate shows that there are about one lakh medical diagnostic laboratories are existing in the country. Enquiries reveal that NABL has accredited around 450 medical laboratories (0.45%), with the rest (99.55%) having only registered themselves with the respective state health departments [2].

The medical laboratories seeking accreditation from NABL are assessed in accordance with ISO 15189:2007. A laboratory wishing to be accredited by NABL must have a Quality Manual on its Quality System satisfying the requirements as described in various clauses of ISO 15189:2007 standards. Quality System documentation and its implementation by the laboratories are verified by its compliance in accordance with ISO 15189:2007 standard. All applications for accreditation shall have to be in accordance with ISO/IEC 17025 or ISO 15189:2007 Standard. Implementation of ISO 15189:2007 standards in help the clinical laboratory to show continual improvement, enhance confidence of the staff and to achieve patient satisfaction. So it would be beneficial for any clinical lab in India to get NABL accreditation [3].

The study was carried out keeping in mind with the objectives to evaluate the quality assurance in clinical biochemistry laboratory as per ISO 15189:2007 standards.

MATERIALS AND METHODS

A prospective observational study was conducted in a tertiary care cardiac center of Southern India. A checklist was prepared based on ISO 15189:2007 standards for assessing the pre-analytical, analytical and post-analytical phases involve in biochemical tests. The criteria employed to record the findings were “Yes”, “No” as the options. A total of 30 blood samples were selected for the assessment of 21

parameters namely Glucose, BUN, Creatinine, Total cholesterol, Triglycerides, Total Bilirubin, Total protein, Albumin, HDL, SGOT, SGPT, Alkaline Phosphatase, GGT, CK, Sodium, Potassium, Chloride, Troponin, T3, T4, TSH. These 21 parameters were evaluated based on the above mentioned three phases. The data collected were analyzed using SPSS 16.0 where the percentage of the values were drawn and presented in the form of table.

RESULTS AND DISCUSSION

A total of 30 blood samples were selected for the evaluation of Pre-analytical, Analytical and Post-analytical phases of biochemical test using 21 parameters. Each phase has been observed and the findings were noted down in the checklist. The findings were then compared with the ISO 15189:2007 standard for NABL accreditation and results were drawn.

The result of each phase is mentioned as hereunder:

Pre-analytical Phase

Pre-analytical process showed 100% compliance with most of the parameters whereas 100% non-compliance had been observed in size of the clinical biochemistry lab premises. Cleanliness of the laboratory, hand washing facilities and adequate manpower at the laboratory showed 60% compliance. The temperature control of collection area found to be 80% compliance, privacy during collection with 40%, completeness of the request forms with 57%, and communication with the patient showed 62% compliance with the set standard of ISO.

Variation were also noticed in transportation of sample where only 50% of the compliance had been observed but very minimal variation of 2% had been observed in transportation of biohazard samples and maintenance of complaint register in the clinical biochemistry laboratory. (Table.1) As per the policy of the hospital and ISOL standard there is a deviation in above mentioned parameters.

Analytical Phase

The result showed the maximum satisfaction in analytical phase with some variation and non-compliance. During observation, 76% of compliance was observed in relation to the organizational hierarchy and safe storage of lab records in the clinical biochemistry laboratory. Regular in-service training showed 74% compliance whereas retention of lab records notice to be only 55% compliant with the standards. A minimum variation of 5% and 9% had been observed in inter-laboratory comparison by external quality assessment schemes and address of deficiency and rectification. (Table.2)

Post Analytical Phase

Evaluation of Post-analytical phase showed maximum variation and non-compliance in most of the parameters. It had been observed that authorization of lab result is maintained only in 90% of cases but it is must for all the lab investigation performed in the laboratory. Reference range of different physiological states was only mentioned in 50% of cases. The Retention and Retrieval of test result for prompt accessibility and the telephonic communication followed by a formal report indicate only 40% compliance with the standards. (Table.3)

CONCLUSION

The ISO 15189:2007 standards are meant to streamline the clinical laboratory process, improve the quality and standardize the procedure of the laboratory of any size. The present study was conducted to determine the compliance of pre-analytical, analytical and post-analytical phase of laboratory test.

This study analyzed all critical stages of lab operations which include pre analytical, analytical and post analytical phases of clinical lab operations. The possible fault has been highlighted at each phases of laboratory process. In order to reduce and control errors in each phase, the lab errors should be monitored on a regular basis. An analysis of documented errors and taking corrective action to prevent the errors in future will provide reliable test results and will help in continual improvement of the each phases of lab testing. Continuous monitoring with respect to NABL standard will help in control of lab errors in all phases of lab testing and would improve the lab functioning.

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Table 1. Evaluation of Pre-analytical Phase (n=21)

Sl. No.	Pre-analytical Component	C (%)	NC (%)
1	Size of premises	0	100%
2	Cleanliness	60%	40%
3	Temperature control collection area	80%	20%
4	Hand-washing	60%	40%
5	Clean toilet facility	100%	0
6	Privacy during collection	40%	60%
7	Request form of lab test	57%	43%
8	Equipment	0	100%
9	Specimen collection requirements	100%	0
10	Expired material in collection area	100%	0
11	Sample collected as per test	100%	0
12	Use of appropriate vacutainer	100%	0
13	Adequate manpower	60%	40%
14	Communication	62%	38%
15	Training of staff	100%	0
16	Ongoing training of staff	90%	10%
17	Identification of staff	100%	0
18	Instruction to patient	100%	0
19	Identification number of sample	100%	0
20	Unique identification to avoid mix-up of samples	100%	0
21	Documentation	100%	0
22	Bar code used	100%	0
23	Universal precaution	100%	0
24	Vaccination	100%	0
25	Disposal of sharp	100%	0
26	Disposal on infectious waste	100%	0
27	Use of leak proof container	100%	0
28	Transportation of samples	50%	50%
29	Transportation of biohazard samples	98%	2%
30	Complaint register	98%	2%

Table 1 shows the pre-analytical components used to evaluate the 21 parameter (n=21) of 30 blood samples. The C (%) and NC (%) represent the Compliance and Non-Compliance percentage of components of parameters against ISO 15189:2007 standard.

Table 2: Evaluation of Analytical Phase (n=21)

Sl. No.	Analytical Component	C (%)	NC(%)
1	Infrastructure	100%	0
2	Emergency backup such as UPS, stabilizers, computers, telephone	100%	0
3	Emergency preparedness	100%	0
4	Facilities for emergency measures	100%	0
5	Electrical equipment comply with safety requirement	100%	0
6	Proper waste disposal	100%	0
7	Labe design and layout suitable for task	100%	0
8	Facilities to monitor, control and record environmental condition	100%	0
9	Storage space	100%	0
10	Cleanliness of work area	100%	0
11	Housekeeping facilities	100%	0
12	Whether the lab director is meeting the responsibility	100%	0
13	Whether organizational hierarchies are defined	100%	0
14	Regular in-service training	74%	26%
15	Orientation of newly recruited staff	100%	0
16	Policy and procedure for purchase	100%	0
17	Quality assessment of the procured items	100%	0
18	Compliance of purchase items with standard requirement	100%	0
19	Safe storage of lab records	76%	24%
20	Retention of records	55%	45%
21	Frequency of internal audit	100%	0
22	Conduct of internal audit by qualified auditors	100%	0
23	Confidentiality of patient reports	100%	0
24	Automated equipment	100%	0
25	Performance of equipment with relevant to lab test	100%	0
26	Calibration of lab equipment	100%	0
27	Maintenance of lab equipment	100%	0
28	Maintenance and functioning of computer and automated system for the integrity of data	100%	0
29	Safeguard of the available systems in lab	100%	0
30	Staff training to operate specific equipment	100%	0
31	Checking of other equipment with regard to accuracy and tolerance	100%	0
32	Accessible of Lab SOP to the staff	100%	0
33	Information available in SOP compliance with QA	100%	0
34	Revision of SOP's	100%	0
35	Use of methods validated and accepted nationally or internationally	100%	0
36	Use of validated procedure for confirming the examination for intended use	100%	0
37	Storage condition of samples	100%	0
38	System for internal quality control	100%	0
39	Well established quality assurance program	100%	0
40	Inter-laboratory comparison by external quality assessment schemes	96%	5%
41	Addressal of deficiencies and rectification	91%	9%

Table 2 shows the analytical components used to evaluate the 21 parameter (n=21) of 30 blood samples. The C (%) and NC (%) represent the Compliance and Non-Compliance percentage of components of parameters against ISO 15189:2007 standard.

Table 3: Evaluation of Post-Analytical Phase (n=21)

Sl. No.	Pre-analytical Component	C (%)	NC (%)
1	Storage of samples with approved policy	100%	0
2	Disposal of samples as per waste management	100%	0
3	Authorization of test results	90%	10%
4	Confidentiality of test result	100%	0
5	Representation of result with appropriate unit	100%	0
6	Integrity of result	100%	0
7	Completeness of test report	100%	0
8	Normal reference range defined	0	100%
9	Reference range for different physiological states were given	50%	50%
10	Communication of urgent test in compliance with hospital policy	100%	0
11	Proper training of staff in handling telephonic request	40%	60%
12	Telephonic communication followed by a formal report	60%	40%
13	Indication of inappropriate sample indicated in the report	40%	60%
14	Retention and Retrieval of test result for prompt accessibility	60%	40%

Table 3 shows the post-analytical components used to evaluate the 21 parameter (n=21) of 30 blood samples. The C (%) and NC (%) represent the Compliance and Non-Compliance percentage of components of parameters against ISO 15189:2007 standard